K123128 page 1/(

510(K) SUMMARY

APR 2 5 2013

SUBMITTED BY:

Company Name:	Allergan
Address:	200 Boston Avenue, Suite 3700 Medford, MA 02155
Telephone:	781-658-2800
Fax:	781-723-7790

CONTACT PERSON:	Connie H. Garrison, MBA, RAC
DATE PREPARED:	March 7, 2013
TRADE NAME:	SERI™ Surgical Scaffold
COMMON and CLASSIFICATION NAME:	Mesh, surgical, absorbable, plastic and reconstructive surgery
CLASSIFICATION REG/PANEL:	CFR §878.3300 / General and Plastic Surgery
PROCODE:	OXF

PREDICATE DEVICES:
K080442 SERI™ Surgical Scaffold
K083898 TEI Biosciences SurgiMend Collagen Matrix
K810428 Ethicon Vicryl Knitted Mesh

DEVICE DESCRIPTION:
SERI™ Surgical Scaffold is a knitted, multifilament, bioengineered, long-term bioresorbable scaffold. It is derived from silk that has been BIOSILK™ purified to yield ultra pure fibroin. The device is a mechanically strong and biocompatible bioprotein. SERI™ Surgical Scaffold is a sterile, single use only product and is supplied in a variety of sizes ready for use in open or laparoscopic procedures. The scaffold is flexible and well-suited for delivery through a laparoscopic trocar. It is tear resistant, with excellent suture retention, and can be cut in any direction. SERI™ Surgical Scaffold provides immediate physical and mechanical stabilization of a tissue defect through its strength and porous (scaffold-like) construction.

SERI™ Surgical Scaffold is designed to slowly bioresorb in parallel to neovascularization and native tissue ingrowth which results in eventual replacement of SERI™ with native tissue. As bioresorption occurs, load bearing responsibility is transferred to the new tissue ingrowth such that mechanical integrity is maintained at the site.

INDICATIONS FOR USE/INTENDED USE:
SERI™ Surgical Scaffold is indicated for use as a transitory scaffold for soft tissue support and repair to reinforce deficiencies where weakness or voids exist that require the addition of material to obtain the desired surgical outcome. This includes reinforcement of soft tissue in plastic and reconstructive surgery, and general soft tissue reconstruction.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Allergan
% Ms. Connie Garrison
200 Boston Avenue, Suite 3700
Medford, Massachusetts 02155-0000

April 25, 2013

Re: K123128
Trade/Device Name: Seri Surgical Scaffold
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: OXF
Dated: March 08, 2013
Received: March 18, 2013

Dear Ms. Garrison:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours, FOR

Peter D. Rümm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K123128

Device Name: SERI™ Surgical Scaffold

Indications for Use:

SERI Surgical Scaffold is indicated for use as a transitory scaffold for soft tissue support and repair to reinforce deficiencies where weakness or voids exist that require the addition of material to obtain the desired surgical outcome. This includes reinforcement of soft tissue in plastic and reconstructive surgery, and general soft tissue reconstruction.

Prescription Use ___X____ AND/OR Over-The-Counter Use___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K123128